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IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ALTANA PHARMA AG and WYETH)	
)	
Plaintiffs)	CIVIL ACTION NO.
)	06-CV-3672 (JLL)
v.)	
)	
KUDCO IRELAND, LTD., KREMERS URBAN)	
DEVELOPMENT CO., SCHWARZ PHARMA, INC.,)	
SCHWARZ PHARMA USA HOLDINGS, INC.,)	
and SCHWARZ PHARMA AG)	
)	
Defendants.)	
)	

**REPLY TO KUDCO IRELAND, LTD. AND
SCHWARZ PHARMA, INC.'S COUNTERCLAIMS**

Plaintiffs Altana Pharma AG and Wyeth (“Plaintiffs”) hereby reply to the counterclaims of defendants Kudco Ireland, Ltd. and Schwarz Pharma, Inc. (“Defendants”). The paragraph numbers used here conform to those used by Defendants in their “Answer and Counterclaims,” dated September 5, 2006.

To the extent any of paragraphs 1-34 of Defendants’ Answer are determined in whole or in part to state counterclaims or the basis for counterclaims, Plaintiffs incorporate by reference paragraphs 1-34 of their Complaint, and deny each and every additional averment contrary to the averments in Plaintiffs’ Complaint contained in Defendants’ paragraphs 1-34.

To the extent any of paragraphs 35-39 of Defendants’ denials and affirmative defenses are determined to state counterclaims, each and every one of the averments therein is denied, except to the extent admitted in Plaintiffs’ responses to paragraphs 1-79 below.

DEFENDANTS’ COUNTERCLAIMS

1. Plaintiffs admit the allegations of paragraph 1.
2. Plaintiffs admit the allegations of paragraph 2.
3. Plaintiffs admit the allegations of paragraph 3.
4. Plaintiffs admit the allegations of paragraph 4.
5. Plaintiffs admit that Defendants purport to claim jurisdiction under various sections of Title 28 of the United States Code. Except as admitted, Plaintiffs deny the allegations of paragraph 5 of the Counterclaims.
6. Plaintiffs admit that there is now a justiciable controversy between Plaintiffs and Defendants concerning the infringement of United States Patent No. 4,758,579. Except as

admitted, Plaintiffs deny the allegations of paragraph 6 of the Counterclaims.

7. Plaintiffs admit the allegations of paragraph 7.

8. Plaintiffs admit that Wyeth Pharmaceuticals, Inc., a wholly-owned subsidiary of Wyeth, holds an approved New Drug Application from the FDA for pantoprazole sodium delayed-release tablets. Except as admitted, Plaintiffs deny the allegations of paragraph 8 of the Counterclaims.

9. Plaintiffs admit that Defendants sent a notice to Plaintiffs in which Defendants represented that they had filed an ANDA for pantoprazole sodium. Except as admitted, Plaintiffs deny the allegations of paragraph 9 of the Counterclaims.

10. Plaintiffs admit that Defendants sent a notice to Plaintiffs in which Defendants represented that they had filed an ANDA for pantoprazole sodium. Plaintiffs admit that Defendants' notice letters were received by Altana on or about July 25, 2006, and by Wyeth on or about July 17, 2006. Except as admitted, Plaintiffs deny the allegations of paragraph 10 of the Counterclaims.

11. Plaintiffs admit that Plaintiffs filed the present action on August 4, 2006, alleging, *inter alia*, infringement of the '579 patent.

COUNT I

12. Plaintiffs reallege each reply to each allegation of paragraphs 1-11 as if set forth specifically here verbatim.

13. Plaintiffs deny the allegations of paragraph 13.

14. Plaintiffs deny the allegations of paragraph 14.

COUNT II

15. Plaintiffs reallege each reply to each allegation of paragraphs 1-11 as if set forth specifically here verbatim.

16. Plaintiffs deny the allegations of paragraph 16.

COUNT III

17. Plaintiffs reallege each reply to each allegation of paragraphs 1-11 as if set forth specifically here verbatim.

18. Plaintiffs state that the '579 patent discloses and claims, *inter alia*, certain compounds useful for inhibiting gastric acid secretion, including pantoprazole sodium. To the extent that paragraph 18 contains any other or inconsistent allegations, Plaintiffs deny each and every one of those allegations.

19. Plaintiffs deny the allegations of paragraph 19.

20. Plaintiffs deny the allegations of paragraph 20.

21. Plaintiffs deny the allegations of paragraph 21.

22. Plaintiffs deny the allegations of paragraph 22.

23. Plaintiffs admit that page 4 of a June 10, 1986 Office Action regarding U.S. Patent Application No. 06/748,591 states, among other things and in the context of other statements and the then-pending claims: "Claims 1-19, 21, 22, 24-25 are rejected under 35 U.S.C. 103 as being unpatentable over pat. 4555518 or 4560693 in view of 4255431." To the

extent that paragraph 23 contains any other or inconsistent allegations, Plaintiffs deny each and every one of those allegations.

24. Plaintiffs deny the allegations of paragraph 24.

25. Plaintiffs deny the allegations of paragraph 25.

26. Plaintiffs deny the allegations of paragraph 26.

27. Plaintiffs admit that page 2 of a October 28, 1986 Office Action regarding U.S. Patent Application No. 06/748,591 states, among other things and in the context of other statements and the then-pending claims: “Claims 1-19, 21, 22, 24, 25-27 are again rejected under 35 USC 103 as being unpatentable over patent 4555518 or 4560693 in view of 4255431 for reasons of record.” To the extent that paragraph 27 contains any other or inconsistent allegations, Plaintiffs deny each and every one of those allegations.

28. Plaintiffs admit that a January 22, 1987 Declaration of Dr. Uwe Krüger was submitted to the Patent Office, and that the declaration includes comparative test data. To the extent that paragraph 28 contains any other or inconsistent allegations, Plaintiffs deny each and every one of those allegations.

29. Plaintiffs admit that Dr. Krüger’s January 22, 1987 Declaration states, among other things and in the context of other statements and the then-pending claims: “the compounds of SN 748,591 have stability characteristics which are unexpectedly superior” To the extent paragraph 29 contains any other or inconsistent allegations, Plaintiffs deny each and every one of those allegations.

30. Plaintiffs admit that Dr. Krüger's January 22, 1987 Declaration states, among other things and in the context of other statements and the then-pending claims that one of the main objects of the invention is to provide compounds which have "a higher chemical stability" and that "such higher chemical stability being expected to correlate with the occurrence of less side effects." To the extent paragraph 30 contains any other or inconsistent allegations, Plaintiffs deny each and every one of those allegations.

31. Plaintiffs admit that in a January 27, 1987 Amendment the patent applicants stated, among other things and in the context of other statements and the then-pending claims, that Dr. Krüger's January 22, 1987 Declaration "provides extensive comparative test data establishing clearly unexpected properties of compounds to which the instantly-asserted claims are limited" To the extent paragraph 31 contains any other or inconsistent allegations, Plaintiffs deny each and every one of those allegations.

32. Plaintiffs admit that Dr. Krüger's January 22, 1987 Declaration states, among other things and in the context of other statements and the then-pending claims: "the compounds of SN 748,591 have stability characteristics which are unexpectedly superior" To the extent paragraph 32 contains any other or inconsistent allegations, Plaintiffs deny each and every one of those allegations.

33. Plaintiffs deny the allegations of paragraph 33.

34. Plaintiffs admit the on February 13, 1987 the patent applications filed a Request for Reconsideration. To the extent paragraph 34 contains any other or inconsistent allegations, Plaintiffs deny each and every one of those allegations.

35. Plaintiffs admit that an April 24, 1987 Declaration of Dr. Uwe Krüger was submitted to the Patent Office, and that it includes comparative test data. To the extent that paragraph 35 contains any other or inconsistent allegations, Plaintiffs deny each and every one of those allegations.

36. Plaintiffs admit that Dr. Krüger's April 24, 1987 Declaration states, among other things and in the context of other statements and the then-pending claims: "compounds of FWC of SN 748,591 have stability characteristics which are unexpectedly superior" To the extent paragraph 36 contains any other or inconsistent allegations, Plaintiffs deny each and every one of those allegations.

37. Plaintiffs admit that Dr. Krüger's April 24, 1987 Declaration states, among other things and in the context of other statements and the then-pending claims: "the chemical stability of the compounds of FWC of SN 748,591 is significantly greater than the stability of the compounds of the prior art." To the extent paragraph 37 contains any other or inconsistent allegations, Plaintiffs deny each and every one of those allegations.

38. Plaintiffs deny the allegations of paragraph 38.

39. Plaintiffs admit that a December 4, 1987 and a February 5, 1988 Declaration of Dr. Krüger, and a December 2, 1987 Declaration of Professor Konrad Heintze were submitted to the Patent Office. Dr. Krüger's Declarations include, among other things, stability data, and Professor Heintze's Declaration includes, among other things, potency data. To the extent paragraph 39 contains any other or inconsistent allegations, Plaintiffs deny each and every one of those allegations.

40. Plaintiffs admit that Professor Heintze's December 2, 1987 Declaration states, among other things and in the context of other statements and the then-pending claims:

"Compounds 14 and 18 (as compared with compounds 12 and 17) can be regarded as being equally potent, compounds 5 and 15 (as compared with compounds 4 and 13) are slightly more potent, compounds 21 and 25 (as compared with compounds 20 and 24) are slightly less potent" To the extent paragraph 40 contains any other or inconsistent allegations, Plaintiffs deny each and every one of those allegations.

41. Plaintiffs deny the allegations of paragraph 41.

42. Plaintiffs admit that Dr. Krüger's January 22, 1987 Declaration states, among other things and in the context of other statements and the then-pending claims that one of the main objects of the invention is to provide compounds which have "a higher chemical stability" and that "such higher chemical stability being expected to correlate with the occurrence of less side effects." To the extent paragraph 42 contains any other or inconsistent allegations, Plaintiffs deny each and every one of those allegations.

43. Plaintiffs deny the allegations of paragraph 43.

44. Plaintiffs deny the allegations of paragraph 44.

45. Plaintiffs deny the allegations of paragraph 45.

46. Plaintiffs deny the allegations of paragraph 46.

47. Plaintiffs admit that some data demonstrated that at ambient temperature, the degradation half-life of pantoprazole sodium is approximately 2.8 hours at pH 5.0. To the extent

paragraph 47 contains any other or inconsistent allegations, Plaintiffs deny each and every one of those allegations.

48. Plaintiffs admit that Wyeth submitted to the FDA some data demonstrating that at ambient temperature, the degradation half-life of pantoprazole sodium is approximately 2.8 hours at pH 5.0. To the extent paragraph 48 contains any other or inconsistent allegations, Plaintiffs deny each and every one of those allegations.

49. Plaintiffs admit that the product labeling for Protonix®, among other things, states: “At ambient temperature, the degradation half-life is approximately 2.8 hours at pH 5.0” To the extent paragraph 49 contains any other or inconsistent allegations, Plaintiffs deny each and every one of those allegations.

50. Plaintiffs admit that the particular data demonstrating that at ambient temperature, the degradation half-life of pantoprazole sodium is approximately 2.8 hours at pH 5.0 was not submitted to the Patent Office, and deny that the ’579 patent applicants had any duty or reason to submit such data to the Patent Office. To the extent paragraph 50 contains any other or inconsistent allegations, Plaintiffs deny each and every one of those allegations.

51. Plaintiffs deny the allegations of paragraph 51.

52. Plaintiffs deny the allegations of paragraph 52.

53. Plaintiffs deny the allegations of paragraph 53.

54. Plaintiffs deny the allegations of paragraph 54.

55. Plaintiffs deny the allegations of paragraph 55.

56. Plaintiffs deny the allegations of paragraph 56.

57. Plaintiffs deny the allegations of paragraph 57.

58. Plaintiffs admit that the '579 patent applicants submitted the results of chemical stability experiments of pantoprazole sodium conducted at room temperature. To the extent paragraph 58 contains any other or inconsistent allegations, Plaintiffs deny each and every one of those allegations.

59. Plaintiffs deny the allegations of paragraph 59.

60. Plaintiffs deny the allegations of paragraph 60.

61. Plaintiffs deny that the '579 patent applicants had a duty to submit to the Patent Office chemical stability experiments of pantoprazole sodium at temperatures higher than room temperature. To the extent paragraph 61 contains any other or inconsistent allegations, Plaintiffs deny each and every one of those allegations.

62. Plaintiffs deny the allegations of paragraph 62.

63. Plaintiffs deny the allegations of paragraph 63.

64. Plaintiffs deny the allegations of paragraph 64.

65. Plaintiffs deny the allegations of paragraph 65.

66. Plaintiffs admit that Australian Patent Application No. 90195/82 and European Patent Application No. 82110054 were filed. To the extent paragraph 66 contains any other or inconsistent allegations, Plaintiffs deny each and every one of those allegations.

67. Plaintiffs admit that Australian Patent Application No. 90195/82 and European Patent Application No. 82110054 contained data from modified-Shay Rat experiments. To the extent paragraph 67 contains any other or inconsistent allegations, Plaintiffs deny each and every one of those allegations

68. Plaintiffs admit that Astra sent letters to the Australian and European Patent Offices that included the publication *Gastric Antisecretory Agents*, Bristol, J.A. *et al.*, J. Med. Chem. (1984). To the extent paragraph 68 contains any other or inconsistent allegations, Plaintiffs deny each and every one of those allegations

69. Plaintiffs deny the allegations of paragraph 69.

70. Plaintiffs deny the allegations of paragraph 70.

71. Plaintiffs admit that on June 19, 1986, Byk Gulden sent a letter withdrawing European Patent Application No. 82110054. To the extent paragraph 71 contains any other or inconsistent allegations, Plaintiffs deny each and every one of those allegations.

72. Plaintiffs admit that Australian Patent Application No. 90195/82 went abandoned. To the extent paragraph 72 contains any other or inconsistent allegations, Plaintiffs deny each and every one of those allegations.

73. Plaintiffs deny that the patent applicants were under any duty to disclose arguments or literature cited by Astra in its December 6, 1985 letter submitted to the Australian patent office or its November 29, 1984 letter to the European patent office. To the extent paragraph 73 contains any other or inconsistent allegations, Plaintiffs deny each and every one of those allegations.

74. Plaintiffs deny the allegations of paragraph 74.

75. Plaintiffs deny the allegations of paragraph 75.

76. Plaintiffs deny the allegations of paragraph 76.

77. Plaintiffs deny the allegations of paragraph 77.

78. Plaintiffs deny the allegations of paragraph 78.

79. Responding to Defendants' Prayer for Relief, Plaintiffs deny that Defendants are entitled to any relief whatsoever, whether as requested or otherwise.

Dated: October 25, 2006

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